

**REMARKS**

In the present Application, Claim 12 has been amended. Claims 12 and 14-25 are currently pending.

The Examiner's rejections are as follows:

(I) Claims 12, 14-18, and 20-25 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Fues et al. (U.S. Pat., 5,143,730) in view of Clark (U.S. Pat. 4,847,083); and

(II) Claim 19 was rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Fues et al. in view of Clark and further in view of Thiele (U.S. Pat. 3,805,776).

Applicants believe the following amendments and remarks traverse the Examiner's rejections of the Claims. These remarks are presented in the same order as the above rejections.

**I. Claims 12, 14-18, and 20-25 are Not Obvious**

The Examiner rejected Claims 12, 14-18, and 20-25 under 35 U.S.C. 103(a) as being unpatentable over Fues et al. (U.S. Pat. 5,143,730) in view of Clark (U.S. Pat. 4,847,083). Applicants respectfully disagree with this rejection.

The Examiner cites Fues et al. as allegedly teaching the compositions recited in the claims and applying the compositions to bones (Office Action, page 3). The Examiner admits, however, that "Fues does not explicitly describe that his compositions would stimulate collagen regeneration in the bone" as indicated by the present claims (Office Action, page 3). The Examiner attempts to make up for this lack of teaching in Fues et al. by alleging that: 1) the compositions of Fues et al. contain lactic acid, 2) that Fues et al. compositions would stimulate collagen regeneration because Clark teaches that lactic acid stimulates collagen formation (Office Action, pages 3-4). Applicants submit that, when the Fues et al. reference is carefully considered, it is clear that the compositions in this reference do not contain lactic acid. As such, the combination of Fues et al. with Clark does not teach all the elements of the present claims as required to establish a *prima facie* case of obviousness.

A careful reading of Fues et al. reveals that the bone wax compositions, while they can be *made* with carboxylic acids (such as lactic acid), only include carboxylic acid *salts*. Indeed, Fues et al. describe as their contribution to the art the use of "suitable bases" to *neutralize* "any free carboxyl groups" present in the starting carboxylic acids to improve the viscosity of the wax compositions (See, Fues et al., Abstract; column 2, lines 62-63; column 3, lines 7-12; and

column 6, lines 57-65). The Example starting at column 6 provides a useful example as it describes how lactic acid was initially present, but was then *neutralized* with calcium carbonate to form calcium lactate, which is the calcium *salt* of lactic acid (See, columns 6-7). As such, the final wax composition contained calcium lactate, not lactic acid.

In light of the above, it is clear that Fues et al. does not teach compositions that contain lactic acid as alleged by the Examiner (see Office Action, page 4). Therefore, combining Fues et al. with Clark et al. does not teach every element of the present claims. As such, the claims should be passed to allowance.

In regard to Clark, Applicants note that this reference does not teach applying a composition to a bone, but instead relates to applying compositions to a tissue. As such, one would not be motivated to combine this reference with the Fues et al. reference. This is an additional reason the Examiner has not established a *prima facie* case of obviousness.

Finally, it is noted that the Clark reference teaches that the phagocytes in certain wounds "tends to reduce the local pH, especially through the production of lactic acid" indicating "[t]his is in itself beneficial, in that lactate is bacteriostatic and also stimulates the formation of collagen" while acknowledging that "lactic acid production may become excessive, causing the area pH to drop to a very low level, thus causing damage to surrounding cells." (Clark, column 2, lines 46-53). In light of this teaching in Clark, in order to *further* distinguish the present claims, and to expedite the prosecution of the present application (while not acquiescing to any of the Examiner's rejections), Applicants have amended the claims. In particular, Claim 12 has been amended to indicate that the stimulation of collagen regeneration in the bone is "by *increasing* the alkalinity in said bone wound with said composition."<sup>1</sup> This amendment further distinguishes over Clark, as the teaching in Clark to decrease the pH for collagen stimulation actually teaches away from the increase in alkalinity recited in the amended claims.

## **II. Claim 19 is Not Obvious**

The Examiner rejected Claim 19 under 35 U.S.C. 103(a) in light of Fues et al. and Clark as applied to Claim 12, and further in view of Thiele (U.S. Pat. 3,805,776). The Examiner cites Thiele for teaching castor oil as part of a bone treating composition (Office Action, page 4).

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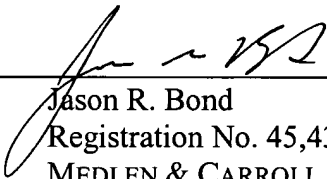
<sup>1</sup> Support for this amendment can be found throughout the application, including on page 5, lines 2-12, Examples 1-5, and Figures 1-4.

Applicants submit that the Examiner has not established a *prima facie* case of obviousness for Claim 12 with the combination of Fues et al. and Clark (e.g. Fues et al. does not teach wax combinations with lactic acid as asserted by the Examiner; there is no motivation to combine Fues et al. and Clark; and Clark teaches away from the increase in alkalinity now recited in Claim 12). The addition of Thiele does not overcome the lack of teaching in these references. As such, for the reasons Claim 12 is not obvious, Claim 19 cannot be obvious. As such, this rejection should be withdrawn.

**Conclusion**

For the reasons set forth above, it is respectfully submitted that Applicants' claims should be passed to allowance. If the Examiner believes an interview would help expedite the allowance of this case, Applicants ask the Examiner to call the undersigned at 608-218-6900.

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